

Food and Drug Administration, HHS

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basis for selecting such methods, devices, and procedures.

(3) For those products displaying aging effects which may increase electronic product radiation emission, records of the results of tests for durability and stability of the product, and the basis for selecting these tests.

(4) Copies of all written communications between the manufacturer and dealers, distributors, and purchasers concerning radiation safety including complaints, investigations, instructions, or explanations affecting the use, repair, adjustment, maintenance, or testing of the listed product.

(5) Data on production and sales volume levels if available.

(b) In addition to the records required by paragraph (a) of this section, manufacturers of products listed in paragraph (c) of § 1002.61 shall establish and maintain the following records with respect to such products:

(1) A record of the manufacturer's distribution of products in a form which will enable the tracing of specific products or production lots to distributors or to dealers in those instances in which the manufacturer distributes directly to dealers.

(2) Records received from dealers or distributors pursuant to § 1002.41.

[38 FR 28625, Oct. 15, 1973, as amended at 60 FR 48386, Sept. 19, 1995]

§ 1002.31 Preservation and inspection of records.

(a) Every manufacturer required to maintain records pursuant to this part, including records received pursuant to § 1002.41, shall preserve such records for a period of 5 years from the date of the record.

(b) Upon reasonable notice by an officer or employee duly designated by the Department, manufacturers shall permit such officer or employee to inspect appropriate books, records, papers, and documents as are relevant to determining whether the manufacturer has acted or is acting in compliance with Federal standards.

(c) Upon request of the Director, Center for Devices and Radiological Health, a manufacturer of products listed in table 1 of § 1002.1 shall submit to the Director, copies of the records

required to be maintained by paragraph (b) of § 1002.30.

[38 FR 28625, Oct. 15, 1973, as amended at 53 FR 11254, Apr. 6, 1988; 60 FR 48386, Sept. 19, 1995]

Subpart E—Dealer and Distributor Records

§ 1002.40 Records to be obtained by dealers and distributors.

(a) Dealers and distributors of electronic products for which there are performance standards and for which the retail price is \$50 or more shall obtain such information as is necessary to identify and locate first purchasers if the product is subject to this section by virtue of table 1 of § 1002.1.

(b) Such information shall include:

(1) The name and mailing address of the distributor, dealer, or purchaser to whom the product was transferred.

(2) Identification and brand name of the product.

(3) Model number and serial or other identification number of the product.

(4) Date of sale, award, or lease.

(c) The information obtained pursuant to this section shall be forwarded immediately to the appropriate manufacturer of the electronic product, or preserved as prescribed in § 1002.41.

[38 FR 28625, Oct. 15, 1973, as amended at 42 FR 18063, Apr. 5, 1977; 60 FR 48386, Sept. 19, 1995]

§ 1002.41 Disposition of records obtained by dealers and distributors.

(a) Information obtained by dealers and distributors pursuant to § 1002.40 shall immediately be forwarded to the appropriate manufacturer unless:

(1) The dealer or distributor elects to hold and preserve such information and to immediately furnish it to the manufacturer when advised by the manufacturer or the Director, Center for Devices and Radiological Health, that such information is required for purposes of section 359 of the Act; and

(2) The dealer or distributor, upon making the election under paragraph (a)(1) of this section, promptly notifies the manufacturer of such election; such notification shall be in writing and shall identify the dealer or distributor and the electronic product or

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products for which the information is being accumulated and preserved.

(b) Every dealer or distributor who elects to hold and preserve information required pursuant to §1002.40 shall preserve the information for a period of 5 years from the date of the sale, award, or lease of the product, or until the dealer or distributor discontinues dealing in, or distributing the product, whichever is sooner. If the dealer or distributor discontinues dealing in, or distributing the product, such information as obtained pursuant to §1002.40 shall be furnished at that time, or before, to the manufacturer of the product.

[38 FR 28625, Oct. 15, 1973, as amended at 42 FR 18063, Apr. 5, 1977; 53 FR 11254, Apr. 6, 1988]

§ 1002.42 Confidentiality of records furnished by dealers and distributors.

All information furnished to manufacturers by dealers and distributors pursuant to this part shall be treated by such manufacturers as confidential information which may be used only as necessary to notify persons pursuant to section 359 of the Act.

Subpart F—Exemptions From Records and Reports Requirements

§ 1002.50 Special exemptions.

(a) Manufacturers of electronic products may submit to the Director a request, together with accompanying justification, for exemption from any requirements listed in table 1 of §1002.1. The request must specify each requirement from which an exemption is requested. In addition to other information that is required, the justification must contain documented evidence showing that the product or product type for which the exemption is requested does not pose a public health risk and meets at least one of the following criteria:

(1) The products cannot emit electronic product radiation in sufficient intensity or of such quality, under any conditions of operation, maintenance, service, or product failure, to be hazardous;

(2) The products are produced in small quantities;

(3) The products are used by trained individuals and are to be used by the same manufacturing corporation or for research, investigation, or training.

(4) The products are custom designed and used by trained individuals knowledgeable of the hazards; or

(5) The products are produced in such a way that the requirements are inappropriate or unnecessary.

(b) The Director may, subject to any conditions that the Director deems necessary to protect the public health, exempt manufacturers from all or part of the record and reporting requirements of this part on the basis of information submitted in accordance with paragraph (a) of this section or such other information which the Director may possess if the Director determines that such exemption is in keeping with the purposes of the Act.

(c) The Director will provide written notification of the reason for any denial. If the exemption is granted, the Director will provide written notification of:

(1) The electronic product or products for which the exemption has been granted;

(2) The requirements from which the product is exempted; and

(3) Such conditions as are deemed necessary to protect the public health and safety. Copies of exemptions shall be available upon request from the Office of Compliance (HFZ-307), Center for Devices and Radiological Health, 2098 Gaither Rd., Rockville, MD 20850.

(d) The Director may, on the Director's own motion, exempt certain classes of products from the reporting requirements listed in table 1 of §1002.1, provided that the Director finds that such exemption is in keeping with the purposes of the act.

(e) Manufacturers of products for which there is no applicable performance standard under parts 1020 through 1050 of this chapter and for which an investigational device exemption has been approved under §812.30 of this chapter or for which a premarket approval application has been approved in